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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/650,337	08/28/2000	William J. Dower	16528A-000461US	8260

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DORSEY & WHITNEY LLP
555 CALIFORNIA STREET, SUITE 1000
SUITE 1000
SAN FRANCISCO, CA 94104

EXAMINER	
HUMPHREY, LOUISE WANG ZHIYING	
ART UNIT	PAPER NUMBER
1648	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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Office Action Summary	Application No.	Applicant(s)	
	09/650,337	DOWER ET AL.	
	Examiner	Art Unit	
	Louise Humphrey, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 October 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *74-76* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *74-76* is/are rejected.

7)☒ Claim(s) *75* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is in response to the amendment filed on 25 March 2006 and 24 October 2006. Claims 1-73 have been cancelled. Claims 74-76 are pending.

Claim Objection

Claim 75 is objected to for containing nucleotide sequences that are not appended with a SEQ ID NO.

New Claim Rejections - Double Patenting

Claims 74-76 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 39 and 40 of US Patent No. 5,723,286 in view of Kauffman *et al.* (US 5,723,323, effectively filed on 20 November 1986).

The instant claims are drawn to a method for identifying a polynucleotide sequence that encodes a peptide which binds to a pre-selected receptor molecule, comprising: transforming host cells with filamentous bacteriophage expression vectors; cultivating the transformed cell under conditions suitable for expression and assembly of bacteriophage particles displaying said peptides on the surface of said particles; selecting bacteriophage particles displaying the peptide bound to the pre-selected receptor molecule; and sequencing said polynucleotide sequence.

The patented claims 1, 39 and 40 differ from the instant claims 74-76 in that they do not recite the last step of polynucleotide sequencing.

Kauffman *et al.* describe a method of isolating a polynucleotide sequence encoding a peptide, polypeptide or protein having a predetermined binding property to a ligand, comprising; (a) providing a ligand for detecting said binding property; (b) synthesizing a diverse population of stochastically generated polynucleotide sequences; (c) inserting said diverse population of stochastically generated polynucleotide sequences into a population of expression vectors to form a diverse population of expression vectors containing stochastically generated polynucleotide sequences; (d) expressing in host cells said diverse population of expression vectors containing stochastically generated polynucleotide sequences to produce a diverse population of peptides, polypeptides or proteins; (e) screening said diverse population of peptides, polypeptides or proteins with said ligand under conditions which allow binding and detection of one or more peptides, polypeptides or proteins to said ligand; and (f) isolating the stochastically generated polynucleotide sequence or sequences which encoding said peptides, polypeptides or proteins having said predetermined binding property to said ligand. The diverse population of polypeptide sequences further comprise greater than about $1x10^8$ different stochastic amino acid sequences. See Claims.

Therefore, it would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to modify the patented invention by adding the step of sequencing the polynucleotide with the selected bacteriophage particles, as described by Kauffman *et al.* One having ordinary skill in the art would have been motivated to make such a modification so that the genetic information from the isolated

polynucleotides can be used to produce peptides, polypeptides or proteins with desired binding properties, as per the suggestion of Kauffman *et al.* There would be a reasonable expectation of success since sequencing technology has been known and routinely practiced in the art. Thus, the invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

New Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. §103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 74 is rejected under 35 U.S.C. §103(a) as being unpatentable over Kauffman *et al.* (US 5,723,323, effectively filed on 20 November 1986) as applied to the double patenting rejection above, and further in view of de la Cruz *et al.* (1988, Ref. No. BG in IDS) and Shigekawa *et al.* (1988, Ref. No. CC in IDS).

The instant invention is a method for identifying a polynucleotide sequence that encodes a peptide which binds to a pre-selected receptor molecule, comprising: transforming host cells with filamentous bacteriophage expression vectors; cultivating the transformed cell under conditions suitable for expression and assembly of bacteriophage particles displaying said peptides on the surface of said particles;

selecting bacteriophage particles displaying the peptide bound to the pre-selected receptor molecule; and sequencing said polynucleotide sequence.

The relevance of Kauffman *et al.* is set forth above. Kauffman *et al.* do not specifically disclose fusion of random peptides with coat proteins in filamentous bacteriophage expression vectors and electroporation of host cells. However, De la Cruz *et al.* describe a method for identifying a polynucleotide sequence that encodes an epitope of circumsporozoite (CS) protein of *Plasmodium falciparum* (peptide to be displayed on the surface of filamentous phage particle by fusion with pIII minor coat protein), which binds to antibodies or antisera (preselected receptor molecule) in rabbits and mice. See Abstract and p. 4318, especially ¶2 and ¶5. Additionally, Shigekawa *et al.* describe electroporation of eukaryotes and prokaryotes. See Title and Abstract.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the Kauffman method by specifically using the filamentous phase display method as taught by de la Cruz *et al.* and the electroporation transformation technique as taught by Shigekawa *et al.* The skilled artisan would have been motivated to do so to increase the efficiency of peptide expression and thereby speed up the selection process. There would have been a reasonable expectation of success, given that the CS protein was efficiently expressed by the phage display technique, as taught by de la Cruz *et al.* Thus, the invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claim 76 is rejected under 35 U.S.C. §103(a) as being unpatentable over Kauffman *et al.* (US 5,723,323) in view of de la Cruz *et al.* (1988), Shigekawa *et al.* (1988), and further in view of Donegan *et al.* (1989).

The instant invention is further limited to immobilizing receptor at reduced densities in subsequent repetitions of the selecting step.

The relevance of Kauffman *et al.*, de la Cruz *et al.*, and Shigekawa et al. is set forth above. None discloses receptor immobilization. However, Donegan *et al.* describe a method for isolation of a species-specific DNA probe for *Neisseria gonorrhoeae* wherein genomic DNA from *N. gonorrhoeae* and *N. meningitidis* (preselected receptor molecules) was immobilized on nitrocellulose filters and probed with recombinant phage DNA from candidate clones (combined with random polynucleotides). Those clones which had hybridized to target sequences were then detected using labeled vector sequences in a second hybridization step. See Abstract.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the Kauffman method by immobilizing preselected receptors, as taught by Donegan *et al.* The skilled artisan would have been motivated to do so for the ease of detection and separation of bound particles from unbound particles, which increases the efficiency of the screening process. There would have been a reasonable expectation of success given that species-specific DNA probe for *Neisseria gonorrhoeae* was isolated, as taught by Donegan *et al.* Thus, the invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Contact Information

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louise Humphrey, Ph.D. whose telephone number is 571-272-5543. The examiner can normally be reached on Mon-Fri, 9:30 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can be reached at 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Jeffrey Parkin, Ph.D.
Primary Examiner
05 January 2007

1/5/07